

Amendment and Response

Serial No.: 09/453,726

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Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Remarks

The Office Action mailed March 28, 2002, has been received and reviewed. The amendment to the specification in Table 1 at page 14, row 3 has been requested simply to correct a typographical error. Exhibit A, a page from the IGN Products Catalog, dated 2002-2003, containing the name, Color Index Number, and chemical composition of the Alkali blue 6B colorant, is submitted herewith as support that Alkali blue 6B is also known in the art as Acid Blue 119. No new matter has been added as a result of this amendment.

The pending claims are claims 1-22. Reconsideration and withdrawal of the rejections in view of the following comments are respectfully requested

The 35 U.S.C. '103 Rejections

The Examiner rejected claims 1-3, 5-13, and 15-22 under 35 U.S.C. §103(a) as being unpatentable over Barrett (U.S. Patent No. 5,955,025) in view of Bealing et al. (U.S. Patent No. 5,990,199).

The Examiner rejected claims 4 and 14 under 35 U.S.C. §103(a) as being unpatentable over Barrett (U.S. Patent No. 5,955,025) in view of Bealing et al. (U.S. Patent No. 5,990,199) and further in view of Patel et al. (U.S. Patent No. 5,053,339).

Applicant respectfully traverses these rejections.

Applicant respectfully points out that Barrett does not disclose an alkali blue colorant in the table at column 3, as suggested by the Examiner. One of the disclosed dyes in the table at column 3, lines 24-30, is a blue colored dye, Reactive Blue BF4R, which is not Alkali blue 6B. Although it is not clear from Barrett, it is believed to be a copper diazo dye (Barrett, column 2, lines 54-56 and column 3, lines 21-30). Alkali blue 6B, as recited in the present claims, is a methane dye. Further, the Alkali blue 6B of the present invention and the Reactive Blue BF4R of Barrett turn different colors upon exposure to a hydrogen peroxide sterilization process. The Reactive Blue BF4R indicator of Barrett turns light grey in the presence of the hydrogen peroxide sterilizing environment of Barrett (Barrett, column 3, lines 2-3 and table),

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while the Alkali blue 6B indicator composition of the present invention turns light grey blue to light blue in the presence of hydrogen peroxide vapor (Specification, page 14, table 1).

The Examiner stated in the Office Action at page 2, line 6 of item 3, that Barrett teaches an "indicator composition including an alkali blue colorant (col.3, table)". Applicant believes this to be a typographical error, as alkali blue colorants are not specifically disclosed in Barrett and, particularly, in view of the Examiner's statement at page 3, lines 2-3 of the Office Action that "Barrett fails to specifically disclose specific examples of alkali blue colorants."

Bealing et al. do not provide that which is missing from Barrett. As the Examiner pointed out, Barrett fails to disclose specific examples of alkali blue colorants (Office Action, page 3, lines 2-3). Combining Bealing et al. with Barrett, however, still would not provide Applicant's indicator composition, as Bealing et al. do not teach the use of Alkali blue 6B (also known as acid blue 119 (see Exhibit A, included herewith)).

Bealing et al. teach the use of certain classes of extractable dyes as indicators (Bealing et al., column 6, lines 32-38). These dyes may be used alone or in combination with non-extractable and/or reactive dyes (Bealing et al., column 6, lines 16-18), wherein the color is removed from extractable dyes during sterilization. The extractable dyes disclosed by Bealing et al. include sodium sulfonate salts of triphenyl methane dyes (Bealing et al., column 6, lines 33-34). Alkali blue 6B (Acid Blue 119), with a chemical composition of $C_{32}H_{29}N_3O_3S$ (Exhibit A), is not a sodium sulfonate salt of a triphenyl methane dye. Further, the disclosed acid blue dyes of Bealing et al. are Acid Blue #7 and Acid Blue #20, not Acid Blue 119. Therefore, Bealing et al. do not provide that which is missing from Barrett, the Alkali blue 6B (Acid Blue 119) colorant.

Additionally, there is no teaching or suggestion in Bealing et al. that the disclosed extractable dyes would be suitable for use in the present invention. Although Bealing et al. disclose that the indicators are intended for use in sterilization processes that include hydrogen peroxide, the indicators are also intended for use under the conditions of heat, pressure, humidity, radiation, ethylene oxide, and combinations of these conditions (Bealing et al., column 5, lines 36-46). Extractable dyes such as those disclosed in Bealing et al. are typically used in steam

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sterilization processes. For indicator compositions using extractable dyes, the extraction step does not occur until the indicator composition has been exposed to temperatures above about 50°C (120°F) (Bealing et al., column 7, lines 60-63). There is no specific teaching or suggestion in Bealing et al. that extractable dyes, typically used in steam sterilization processes, would be suitable as indicators of a hydrogen peroxide sterilization process.

Further, there is no indication that an indicator composition intended for use in heat sterilization processes would be suitable for use as an indicator for a hydrogen peroxide sterilization process. Bealing et al. teach that chemical indicators are designed to react to the critical parameters associated with a particular sterilization process, and that there are at least as many variations of chemical indicator compositions as there are sterilization processes (Bealing et al., column 2, lines 30-33). This is illustrated by the examples of Bealing et al., which show various sterilization processes used with various indicator compositions. In example 5, for instance, the indicator composition showed an initial color of blue and a signal color of violet for a steam sterilization process, but either remained blue or changed to green when exposed to an ethylene oxide sterilization process. Additionally, none of the sterilization processes of the examples included hydrogen peroxide sterilization processes, and none of the indicator compositions included an extractable dye. As there is no teaching of the use of extractable dyes as indicators for hydrogen peroxide sterilization processes, and no suggestion that extractable dyes would be successful if used in hydrogen peroxide sterilization indicators, Applicant respectfully submits there is no motivation to combine Bealing et al. with Barrett to provide indicator compositions and methods for hydrogen peroxide sterilization processes of the present invention.

Patel teaches a color changing device for monitoring the shelf life of products. The device may include an oxidizing agent that can oxidize a reduced dye to introduce a color change (Patel, column 11, lines 47-48). Common representative oxidizing agents include hydrogen peroxide (Patel, column 11, lines 56-57 and 61). There is no teaching or suggestion in Patel of a sterilization indicator or a method of monitoring a hydrogen peroxide sterilization

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process. Further, there is no teaching or suggestion of the use of Alkali blue 6B in a hydrogen peroxide sterilization indicator composition. Therefore, Patel does not provide that which is missing from Barrett or Bealing et al., either alone or in combination.

Applicant, in view of the foregoing comments, respectfully requests reconsideration and withdrawal of the rejections.

Art made of record but not relied upon

Applicant's Representatives note the art made of record but not relied upon: Ignacio (U.S. Patent No. 6,063,631). However, Applicant's Representatives respectfully point out that while Ignacio teaches the use of aniline blue in Example 5, Ignacio does not teach the use of alkali blue.

International Search Report and Written Opinion

Applicant herewith submits a copy of an International Search Report and a Written Opinion issued in an application related to the above-identified application. The art cited therein has already been submitted to the Examiner in previously filed Information Disclosure Statements.

Summary

It is respectfully submitted that the pending claims 1-22 are in condition for allowance and notification to that effect is respectfully requested.

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The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

David M. READ

By Mueting, Raasch & Gebhardt, P.A.
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Minneapolis, MN 55458-1415
Phone: (612) 305-1220
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Customer Number 26813

**26813**

PATENT TRADEMARK OFFICE

Date

June 28, 2002

By:

Ann M. Mueting

Reg. No. 33,977

Direct Dial (612)305-1217

CERTIFICATE UNDER 37 CFR 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR 1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this 28th day of June, 2002, at 5:15 pm (Central Time).

By:

Name: KATHLEEN L. FRANKLIN

**APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

Serial No.: 09/453,726

Docket No.: 52951US002

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been marked in bold typeface.

In the Specification

The portion of Table 1 at page 14 of the specification has been amended as indicated on the following page:

Page 2 of 2

Amendment and Response - Appendix A
 Applicant(s): David M. READ
 Serial No.: 09/453,726
 Confirmation No.: 2987
 Filed: 2 December 1999
 For: HYDROGEN PEROXIDE INDICATOR AND METHOD

17	¹ Lissamine green B (<i>Acid Green</i> 50 or <i>Wool</i> <i>Green S</i>)	Methane	44090	Blue (teal)	Slightly lighter	Pale blue
18	² Alkali blue 6B (<i>Acid Blue [110]</i> <i>119</i>)	Methane	[42750] <u>42765</u>	Blue	Light grey blue	Light blue
19	¹ Brilliant Green (<i>Basic Green I</i>)	Methane	42040	Green	Pale green	Colorless

¹Commercially available from Sigma-Aldrich Fine Chemicals, St. Louis, MO.

²Commercially available from ICN Biomedicals, Costa Mesa, CA.

EXHIBIT

A

ION

Alphabetical List of Products

Alph

CATALOG
NUMBER

153939

0-5°C

ALDOCLASE

(D-Fructose-1,6-bisphosphate-D-
glyceroldehyde-3-phosphate lyase; E.C.
4.1.2.13)

From Rabbit Muscle

Lyophilized powder containing sucrose

as a stabilizer.

Activity: ~10 units/mg protein

Unit Definition: one unit is the change

in absorbance of 1.00 per minute at

25°C, pH 7.5.

Protein From Moisture

25 mg

100 mg

US\$

\$2.40

\$5.80

CATALOG
NUMBER

180092

RT

ALIZARIN COMPLEXONE

(3558-78-1)
(Alizarin Fluorine Blue; Alizarin-3-
methylamino-N,N-dimethyl Acid)
C₁₅H₁₀N₂O₆ MW 385.3

1 g

25.25

5 g

65.10

100 g

141.70

CATALOG
NUMBER

180975

RT

ALIZARIN RED S

(130-22-3)
Alizarin Sodium Sulfonate
Indicator, pH Range 5.7 - 6.2
C₁₅H₈O₆Na₂ MW 342.3

25 g

24.30

100 g

89.96

500 g

319.70

CATALOG
NUMBER

154728

RT

ALIZARIN VIOLET R

(8408-63-4)
Dye content: ~ 60%
C₁₅H₈O₆Na₂ MW 342.3

5 g

15.75

25 g

43.90

CATALOG
NUMBER

158222

RT

ALIZARIN YELLOW R

(1718-34-9)
(Mordant Orange 1)
C.I. 14030
Dye Content: ~ 80%
C₁₅H₈O₆Na₂ MW 342.3

10 g

9.55

25 g

18.25

100 g

43.10

CATALOG
NUMBER

152627

RT

ALKALI BLUE 4B

(82152-67-4)
(Acid Blue 170)
C.I. 42760
Dye content: ~ 40%
C₁₅H₈O₆Na₂ MW 342.3

25 g

33.95

100 g

123.55

CATALOG
NUMBER

152628

RT

ALKALI BLUE 8B

C.I. 42765
(Acid Blue 119)
Dye content: ~ 60%
C₁₅H₈O₆Na₂ MW 342.3

10 g

14.30

CATALOG
NUMBER

140774

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From *E. coli*
Partially purified; suspension in
ammonium sulfate, pH 7.0, containing
Activity: 10 units/mg
Unit Definition: One unit hydrolyzes 1
μmole of p-nitrophenyl phosphate per
minute.

100 U

61.80

500 U

202.70

1 KU

835.65

CATALOG
NUMBER

103288

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From Chicken Intestine
Salt-Free
Lyophilized powder
Activity: 0.0-2.2 units/mg dry wt.
Unit Definition: 1 unit hydrolyzes one
micromole of o-carboxyphenyl
phosphate per minute at pH 8.6 and
25°C.

250 mg

31.50

1 g

50.40

5 g

304.60

CATALOG
NUMBER

150031

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From Chicken Intestine
(E.C. 3.1.3.1)
A purified suspension in 0.2 M
Ammonium sulfate, pH 7.0, containing
0.0001 M MgCl₂ and 0.001 M ZnCl₂.
Activity: 500-800 units/mg protein.
Unit Definition: One unit causes
hydrolysis of one micromole of p-
nitrophenyl phosphate per minute at pH
8.6 and 25°C.

1 KU

27.00

5 KU

100.00

10 KU

188.00

25 KU

432.00

CATALOG
NUMBER

153006

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From Cat Intestine
E.C. 3.1.3.1
Supplied in 50% glycerol, containing 5
mM Tris, 0.005 M magnesium chloride
and 0.0001 M zinc chloride, pH ~7.0
Activity: ~21600 U/mg protein
Unit Definition: One unit causes
hydrolysis of one micromole of p-
nitrophenyl phosphate at pH 8.6 and
25°C.
This is the highest activity material
available anywhere. Many others claim
high activity (1100-1200 U/mg) but the
assays are at 37°C. We have not seen
any other material comparable to this
both high purity and activity.CATALOG
NUMBER

150189

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From Cat Intestine
E.C. 3.1.3.1
A highly purified suspension in 70%
ammonium sulfate, pH 7.0, containing
0.001 M MgCl₂ and 0.001 M ZnCl₂.
Activity: 500-900 units/mg protein
Unit Definition: One unit causes
hydrolysis of one micromole of p-
nitrophenyl phosphate per minute at pH
8.6 and 25°C.CATALOG
NUMBER

150273

0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
From Cat Intestine
E.C. 3.1.3.1
Activity: ~1500 units/mg protein
Unit Definition: the amount of
enzyme causing the hydrolysis of one
micromole of p-nitrophenyl phosphate per
min. pH 8.6, at 25°C.
Supplied in a highly purified, salt-free,
stabilized solution of 5 mM MgCl₂, 0.1
mM ZnCl₂, 5 mM Tris and 50% glycerol.
Protein concentration 10-20 mg/ml.CATALOG
NUMBER

150347

RT

ALKALINE PHOSPHATASE

(9001-78-9)
From Cat Intestine
Conjugation Grade
Freezed dried.
Activity: 1500 U/mg.
Unit Definition: One unit will liberate
one micromole of p-nitrophenol per
minute at 37°C, pH 10.15 in Tris buffer.CATALOG
NUMBER

150558

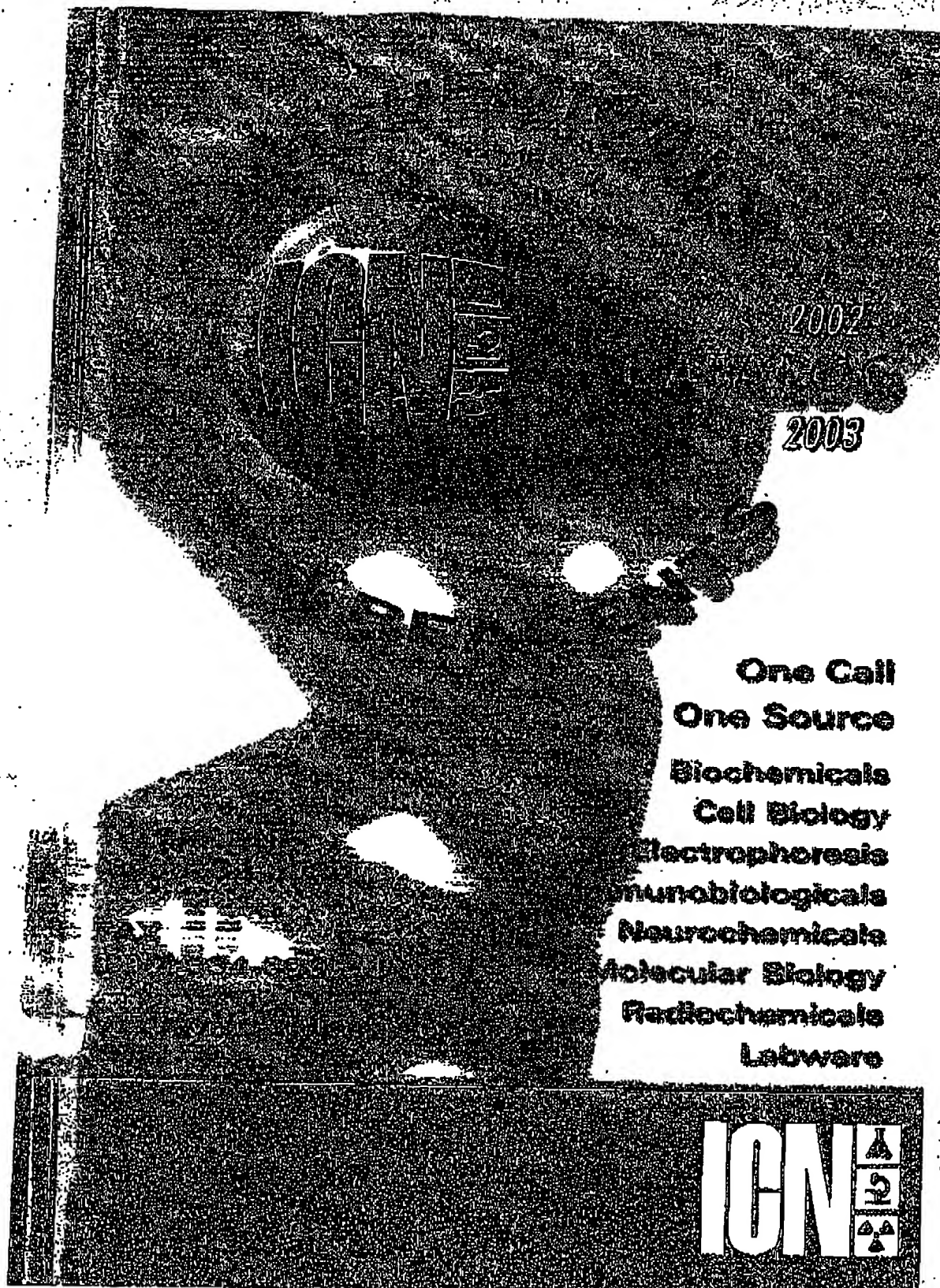
0-5°C

ALKALINE PHOSPHATASE

(9001-78-9)
(Orthophosphoric Monocester
Phosphohydrolase; E.C. 3.1.3.1)
From Cat Intestine
Freezed dried powder.
Activity: ~1.0 units/mg
Unit Definition: One unit causes
hydrolysis of one micromole of p-
nitrophenyl phosphate per minute at pH
8.6 and 25°C.To place an order, (800) 854-0530, fax (800) 334-6999
Outside the U.S.: (330) 562-1500, fax (330) 562-1507

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From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
OFFICE OF INTELLECTUAL PROPERTY COU
NSEL
Attn. BURTIS, John A.
Post Office Box 33427
Saint Paul, Minnesota 55133-3427
UNITED STATES OF AMERICA

RECEIVED

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

MAR 27 2001

(PCT Rule 44.1)

John A. Burtis

5/22/01

Date of mailing
(day/month/year)

22/03/2001

Applicant's or agent's file reference

52951PCT5A

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US 00/31847

International filing date
(day/month/year)

20/11/2000

Applicant

3M INNOVATIVE PROPERTIES COMPANY

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the International application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the International application, or of the priority claim, must reach the International Bureau as provided in Rules 90b/s.1 and 90b/s.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for International preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Petronella Vaassen-Elsackers

Form PCT/ISA/2001 (July 1999)

Received from <6123051228> at 6/28/02 6:10:13 PM [Eastern Daylight Time]

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?**Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 52951PCT5A	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/31847	International filing date (day/month/year) 20/11/2000	(Earliest) Priority Date (day/month/year) 02/12/1999
Applicant 3M INNOVATIVE PROPERTIES COMPANY		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

PCT/US 00/31847

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N31/22 A61L2/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 955 025 A (BARRETT RICHARD B) 21 September 1999 (1999-09-21) the whole document	1-20
X	WO 98 52621 A (MINNESOTA MINING & MFG) 26 November 1998 (1998-11-26) claims 1-5 example 1	1-5, 9, 11-15, 19, 20
P, X	WO 00 61200 A (PATEL GORDHANBHAI N) 19 October 2000 (2000-10-19) table 2 page 17, line 21 - line 27 example 3 claims	1-6, 9-16, 19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

15 March 2001

Date of mailing of the international search report

22/03/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Muñoz, M

PCT/US 00/31847

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5955025	A	21-09-1999	NONE		
WO 9852621	A	26-11-1998	US	6063631 A	16-05-2000
			AU	7581498 A	11-12-1998
			EP	0984792 A	15-03-2000
WO 0061200	A	19-10-2000	AU	4336700 A	14-11-2000

Form PCT/ISA/210 (patent family annex) (July 1992)

PATENT COOPERATION TREATY

R 66 p

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

100.52951020

PCT

WRITTEN OPINION

(PCT Rule 66)

To:

VOSSIUS & PARTNER
P.O. Box 86 07 87
D-81634 München
ALLEMAGNEEINGEGANGEN
Vossius & Partner

07. Dez. 2001

Frist
beacht.

6.2.

16.1.02

Date of mailing
(day/month/year)

06.12.2001

Applicant's or agent's file reference

F 1624 PCT

REPLY DUE

within 2 month(s)
from the above date of mailing

2/6/02

International application No.

PCT/US00/31847

International filing date (day/month/year)

20/11/2000

Priority date (day/month/year)

02/12/1999

International Patent Classification (IPC) or both national classification and IPC

G01N31/22

Applicant

3M INNOVATIVE PROPERTIES COMPANY

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 88.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain document cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 65.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 02/04/2002.

Name and mailing address of the international
preliminary examining authority:European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
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Authorized officer / Examiner

Komenda, P

Formalities officer (incl. extension of time limits)

Conner, M

Telephone No. +49 89 2399 2241



WRITTEN OPINION

International application No. PCT/US00/31847

1. Basis of the opinion

1. With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"):

Description, pages:

1-18 as originally filed

Claims, No.:

1-20 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the International search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 49.3(b)).
☐ the language of a translation furnished for the purposes of International preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

WRITTEN OPINIONInternational application No. **PCT/US00/31847**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- | | |
|-------------------------------|-------------|
| 1. Statement | |
| Novelty (N) | Claims |
| Inventive step (IS) | Claims 1-20 |
| Industrial applicability (IA) | Claims |

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US00/31847

Section V:

1. Reference is made to the following documents:

✓ D1 = WO 98/52621

✓ D2 = WO 00/61200

2. Document D1 represents the nearest available prior art with respect to independent claim 1 and reveals a hydrogen peroxide indicator comprising a substrate and an indicator composition disposed thereon. In one embodiment the indicator composition comprises the colorant acid fuchsin (example 1). The colorant basic fuchsin is also exemplified (example 2).

Independent claim 1 mentions a list of possible colorants to be used in said indicator composition, amongst others new fuchsin is exemplified. The difference between the H_2O_2 indicator of D1 and that of claim 1 is that the dye acid fuchsin (basic fuchsin) is replaced by new fuchsin i.e. a derivative of the same "dye family". No particular technical effect can be recognised in using new fuchsin instead of e.g. acid fuchsin. The technical problem to be solved is thus to provide another H_2O_2 indicator.

The technically skilled person appears to be well aware of indicator dyes which change colour upon contact with H_2O_2 , in particular those belonging to the same type of dye. It would thus be obvious for him to replace the dye known from D1 by an alternative H_2O_2 sensitive dye and in doing so he would arrive at the subject-matter of claim 1 without any need of performing an inventive step (Article 33(3) PCT).

The same considerations apply to the other alternatives of claim 1.

3. Document D1 also describes the use of a binder in the indicator composition and the use of a second colorant which does not change colour upon contact with H_2O_2 (see page 3, 1st and 3rd paragraphs). For reasons similar to those given above the subject-matter of claim 10 also appears to lack an inventive step over D1 (Article 33(3) PCT).

The same holds for the use of the non-inventive H_2O_2 indicator in a known sterilisation process as defined in independent claim 11.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US00/31847

4. The features of dependent claims 9, 19 and 20 are also known from D1 and thus add nothing inventive to the claims to which said claims refer.

The H₂O₂ indicators using the dyes mentioned in the other claims are considered obvious for the same reasons as given with respect to the independent device claims.

Section VI:

Although document D2 does not constitute prior art within the meaning of Rule 64.1 b) PCT it is to be noted, that the disclosure of said document is novelty destroying at least for the subject-matter of claim 1 for those embodiments employing dyes nos. 1-8, 16-19, 22-24, 29-31, 33, 36, 43 and 44 (numbers according to tables 1 and 2 of the description) (for D2 see pages 9-11, table 2).

It should be mentioned here, that the validity of the claimed priority date has not been checked.

Section VII:

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
2. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
3. The unit "inch" employed in the description (page 4) is not additionally expressed in terms of the units stipulated by Rule 10.1/(a)/and/(b) PCT.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US00/31847

4. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

Section VIII:

1. From tables 1 and 2 it is apparent that some of the claimed indicators comprise colorant dyes which give no colour change upon contact with H_2O_2 . It is thus not apparent how such an embodiment could technically be reproduced. Claim 1 thus encompasses subject-matter which is not sufficiently disclosed within the meaning of Article 5 PCT.
2. It appears that those dyes of claim 1 for which not colour index exists do not have a well recognised meaning in the particular art. The skilled person would thus appear not to be able to unambiguously determine the correct compounds to which said unclear terms relate.
3. There is no antecedent basis for "the colorant" in claim 12. The same holds for claims 13-15, 16 and 18 ("indicator composition").